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09/677,752	10/02/2000	W. James Jackson	2479.0050000	5261

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/677,752	JACKSON, W. JAMES	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *94,95,99-103,105-107 and 131-146* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *94,95,99-103,105-107 and 131-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The request for continued examination filed October 31, 2007 has been entered.

Applicant's amendment filed November 16, 2007 and December 7, 2007 have been acknowledged and entered. Applicant's declaration submitted by W. James Jackson filed under 37 C.F.R. 1.132 and Exhibits A-H filed November 16, 2007 are acknowledged. Claims 1-93, 96-98, 104 and 108-130 have been canceled. Claims 131-146 have been added. Claims 94-95, 99-103, 105-107 and 131-146 are under examination.

Declaration

2. The declaration submitted by W. James Jackson filed under 37 CFR 1.132 and Exhibits A-H filed November 16, 2007 are insufficient to overcome the art rejections. However, as indicated below, Applicant's amendments to the claims filed December 7, 2007 are persuasive and the art rejections are withdrawn.

Information Disclosure Statement

3. The information disclosure statement filed October 31, 2007 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. Applicant should submit a 1449 form along with a copy of the references to be considered. The information disclosure statement filed October 31, 2007 has been placed in the application file, but the information referred to therein has not been considered.

Rejections Withdrawn

4. In view of Applicant's amendment the following rejections are withdrawn:

(a) rejection of claims 107-108, 111-112, 115-116, 118-124, 126-127 and 130 under 35 U.S.C. 112 first paragraph, pages 3-7, paragraph 3 of the Final Office action.

(b) rejection of claims 107, 111-112, 115-116, 118-124 and 130 under 35 U.S.C. 102(b), pages 7-9, paragraph 4 of the Final Office action.

(c) rejection of claims 107-108, 111-112, 115-116, 118-124 and 130 under 35 U.S.C. 102(a), pages 9-11, paragraph 5 of the Final Office action.

(d) rejection of claims 107-108, 111-112, 115-116, 118-124 and 130 under 35 U.S.C. 102(a), pages 11-13, paragraph 6 of the Final Office action.

(e) rejection of claims 107-108, 111-112, 115-116, 118-124, 126-127 and 130 under 35 U.S.C. 103(a), pages 14-16, paragraph 7 of the Final Office action.

(f) objection to claim 120, pages 16-17, paragraph 8.

Claim Objection

5. Claim 94 is objection to because of the following informality: claim 94 has a period after the term "encoded" which is within the middle of a sentence. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit

6. Claims 139-146 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because it is not clear that cell lines possessing the properties of plasmid M15pReP(pQE-pmpE Ct)#37 deposited under ATCC accession no. PTA-2462 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above plasmid M15pReP(pQE-pmpE Ct)#37 deposited under ATCC accession no. PTA-2462 one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of plasmid M15pReP(pQE-pmpE Ct)#37 deposited under ATCC accession no. PTA-2462 on pages 57-58 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met. If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this

specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
>
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
>
> (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
>
> (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test

must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid M15pReP(pQE-pmpE Ct)#37 deposited under ATCC accession no. PTA-2462 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Scope of Enablement Regarding Fragments

7. Claims 134 and 142 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *Chlamydia trachomatis* high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP), does not reasonably provide enablement for fragments of the *Chlamydia trachomatis* high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches that compositions comprising PMPE proteins of the invention and the other immunogens such as the *Chlamydia trachomatis* high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP) (page 43). The claims are directed to sequences that are fragments of the *Chlamydia trachomatis* high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP), There is no guidance provided as to which amino acids can be deleted and still have the polypeptide retain its biological function. Thus, the resulting polypeptide could result in a polypeptide not taught nor enabled by the specification.

Thomas E. Creighton, in his book, "*Proteins: Structures and Molecular Properties, 1984",* (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a proline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "*Protein Structure: A Practical Approach, 1989; pages 184-186"* teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "*Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph)* adds support to Thomas E. Creighton, by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly

encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in an amino acid's sequence and still retain similar activity requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide's structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would not expect any tolerance to multiple deletions. There is no guidance provided in the specification as how one would begin to choose "fragments" of the *Chlamydia trachomatis* high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP),. The specification

does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does not disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of sequence(s) which can be predictably modified and which regions are critical;
- what fragments, if any, can be made which the retain the biological activity if the intact polypeptide; and
- the specification provides essentially no guidance as to which of the essentially infinite possible choice is likely to be successful.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other polypeptides having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptide that are fragments of the *Chlamydia*

trachomatis high molecular weight protein (HMW) or the *Chlamydia* major outer membrane protein (MOMP), in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The Applicant has not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of deletions or fragments of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the polypeptide's structure and still maintain activity is unpredictable and the experimentation left those skilled in the art is unnecessarily and improperly, extensive and undue. See Amgen Inc v Chugai Pharmaceutical Co Ltd. 927 F 2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Exparte Forman, 230 U.S. P.Q. 546(Bd. Pat=. App & int. 1986).

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the claimed invention commensurate in scope with the claims.

Scope of Enablement Regarding Vaccine Compositions

8. Claims 94, 95, 99-103, 106-107 and 131-146 rejected under 35 U.S.C. 112, first paragraph, because the specification, while enable for immunogenic compositions that produce an immune response in a subject does not provide enablement for a *vaccine compositions* wherein the effective amount of said vaccine composition administered to

subjects provide *protective immunity.* In the case of independent claim 107, the specification does not provide enablement for recited limitation "wherein an effective amount of said vaccine administered to female mice reduces *Chlamydia trachomatis*-induced infertility. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Independent claim 94 is directed to a vaccine comprising an isolated recombinant PMPE polypeptide comprising a polypeptide encoded by a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO;1 fused to a nucleic acid molecule encoding a histidine affinity ($(H)_6$) domain.

Independent claim 95 is directed to a vaccine comprising an isolated recombinant PMPE polypeptide comprising the amino acid sequence of SEQ ID NO:2 fused to an amino acid sequence comprising a histidine affinity ($(H)_6$) domain.

Independent claim 107 is directed to a vaccine comprising an isolated polypeptide comprising the mature putative membrane protein E (pmpE) encoded by SEQ ID No.2 and a carrier wherein an effective amount of said vaccine administered to female mice reduces *Chlamydia trachomatis*-induced infertility.

Independent claim 139 is directed to vaccine comprising an isolated polypeptide comprising the mature putative membrane protein E (pmpE) inserted in plasmid M15pREP (pQE-pmpE Ct) #37 deposited under ATCC Accession No. PTA-2462 and a carrier wherein an effective amount of said vaccine administered to female mice reduces *Chlamydia trachomatis*-induced infertility.

The specification fails to enable the claimed vaccine compositions encompassed by the claims. The term *"vaccine"* encompasses the ability of the specific antigen to *induce protective immunity* to *Chlamydia* infection or disease induction. The specification at section 6.9 discloses in an *in vitro* neutralization model and a mouse model of salpingitis and fertility. The Examples do not disclose any data as a result of the disclosed experiments. The only data disclosed in regards to these experiments is represented in Figure 7. Figure 7 merely shows that T-cell proliferation (e.g. immune responses were induced). There is no data disclosed in the instant specification leading one of skilled in the art to conclude that the instant specification shows that the claimed vaccine compositions are protective.

The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of protecting against *Chlamydia* infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccine compositions , i.e. would not be able to accurately predict if protective immunity has been induced. The specification further does not disclose any examples demonstrating *in vivo* use of the claimed polypeptides. An *in vivo* example, would aid in answering question such as what mode of administration of the claimed polypeptides can be used to ensure that the claimed polypeptides reach the target organs in order to protect against *Chlamydia* infections?

The ability to reasonably predict the capacity of a single bacterial immunogen or combinations of immunogens to induce protective immunity against *Chlamydia* infection is problematic. Longbottom et al *(Journal of Medical Microbiology 52, p. 537-540)* teach in terms of *Chlamydia* animal infections there are problems associated with asymptomatic infections (page 537). Longbottom et al teach that the relative contribution of antibody to resolve *Chlamydia* infections is still a matter of debate (page 538). Longbottom et al teach that studies in guinea pig models for human genital tract infections have demonstrated a role for antibody in *limiting* primary infections (page 538). Longbottom et al teach that *there is no requirement for antibody* in murine models (page 538).

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Based on the teaching of the cited art, it is unclear as to whether antibodies have a role in protecting against *Chlamydia* infections. The instant specification has shown that there are cellular and humoral immune responses elicited when animals are administered the polypeptides of the invention. However, the specification has failed to show that these polypeptides provide protection against *Chlamydia* disease or infection

when administered to animals. Thus, the specification does not provide enablement for the claimed vaccine compositions encompassed by the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to developing a *Chlamydia* vaccine that would achieve a desire level of success when administered to a patient with *Chlamydia* infections, 3) there are no working examples which suggest the desired results of a successful vaccine composition that can protect against *Chlamydia* infection, 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level), and the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 106, 134 and 142 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite "HMW". The instant specification does not define "HMW" or High molecular weight polypeptides. It is unclear as to what the molecular weight ranges are for these polypeptides. How is the molecular weight determined for these HMW polypeptides? Correction is required.

10. Claims 107 and 131-133 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 107 recites the claim limitation "...mature putative membrane protein E...". It is unclear as to what Applicant intends by this recitation. What is the structure of the mature putative membrane protein E? What amino acids are required? Clarification/correction is required.

11. Claims 107, 131-133 and 141-144 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 107 and 141 recite the claim limitations

"…pre or pro-sequence…" and "…immunogenic sequence". It is unclear as to what Applicant intends by these recitations. What is the structure of the claimed pre-sequence, pro-sequence or immunogenic sequence? What amino acids are required?

12. Claims 136 and 144 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 136 and 144 contains trademarks, (e.g. Ribi DETOX™). The components in these adjuvants or concentrations of the adjuvants may vary, therefore the use of trademarks in a particular vaccine composition should be deleted from the claims. Correction is required.

13. Claims 107 and 131-138 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 107 recites the claim limitation an isolated polypeptide comprising the mature putative membrane protein E (pmpE) encoded by SEQ ID NO:2. It should be noted that *SEQ ID NO:2 is an amino acid sequence and cannot encode a polypeptide*. Correction is required.

14. Claim 138 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 138 recites the "bacterial toxin or fragment thereof…". It is unclear

as to what Applicant intends by a fragment of a bacterial toxin What amino acids are required for this structure? Clarification/correction is required.

Status of Claims

15. No claims are allowed.

16. The claims appear to be free of the prior art.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
March 10, 2008

/N. M. Minnifield/

Primary Examiner,

Art Unit 1645